

## **REMARKS**

Claims 20-53 are pending in the application, claims 48-53 being newly added herein. Claims 1-19 have been canceled without prejudice to refiling the claims in a divisional application. Claims 20, 30, 44, and 45 are the only independent claims.

### ***Specification***

The specification has been amended to provide clear antecedent basis for language used in new claims 48-51. The new language describes obvious and apparent features of the invention from the disclosure taken as a whole, and particularly from the drawings.

### ***Claims Rejections - 35 U.S.C. § 103***

Claims 20-30 and 35-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,655,698 to Yoon in view of U.S. Patent No. 457,787 to Leisenring.

Applicant respectfully traverses the rejection of claims 20-30 and 35-47 for reasons set forth below. Applicant accordingly requests reconsideration of claims 20-30 and 35-47.

**Independent Claim 20** As set forth in claim 20, a method for the treatment of hemorrhoids, in accordance with the present invention, utilizes an anoscope and a hemorrhoid occlusion device. The anoscope includes a hollow body having a sidewall provided with a window, while the hemorrhoid occlusion device has a distal end provided with a pair of jaws, at least one of the jaws including a C- or U-shaped clamping member. The method includes (i) inserting the anoscope into an anal canal, (ii) manipulating the anoscope so that hemorrhoidal tissues protrude through the window into the anoscope, (iii) inserting the jaws of the occlusion device into the anoscope, (iv) manipulating the occlusion device, after the protruding of the hemorrhoidal tissues through the window and after the inserting of the jaws into the anoscope, so that the jaws are located on

opposite sides of the hemorrhoidal tissues, (v) thereafter closing the jaws to clamp the hemorrhoidal tissues, and (vi) subsequently operating a tissue occlusion component of the occlusion device to permanently constrict a portion of the hemorrhoidal tissues.

The Yoon reference discloses several embodiments of a stapling device, including a scissors or pliers model shown in Figure 1, a laparoscopic or endoscopic version shown in Figure 20, an elongate version shown in Figures 23 and 24, a version with U-shaped jaws shown in Figure 28 and additional pliers-type models shown in Figures 33 and 35. The closest to applicant's closure device (when a stapler) is that of Figure 28.

Leisenring discloses a rectal speculum, a short rigid tubular member, closed at a distal end for insertion into the rectum. The speculum of Leisenring is used to perform medical procedures on the rectal portion of the colon under direct observation.

Applicant respectfully traverses the rejection of claims 20-30 and 35-47 under 35 U.S.C. § 103(a) because the references relied on by the Examiner provide *no motivation* to use the stapler of Yoon with the speculum of Leisenring. Yoon simply says nothing about using his stapler to treat hemorrhoids. Leisenring speaks about using the speculum in the treatment of hemorrhoids, but specifically mentions only needles in a treatment procedure. Leisenring says nothing about *occluding* hemorrhoids, as contemplated by applicant. Moreover, Leisenring appears to *teach away* from such a violent procedure as stapling hemorrhoids, since Leisenring expresses concern about injuring or damaging the intestinal tissues: "...as, instead of presenting a single open slot, several shorter slots are provided, there will be less liability of injury to the patient due to the pressure of the intestine into the slot of the instrument" (page 2, lines 12-17).

Finally, even if the references relied on by the Examiner provided a suggestion of occluding hemorrhoidal tissues, one of ordinary skill in the art would be dissuaded from using the various staplers of Yoon with the speculum of Leisenring since the Yoon staplers are not adapted to working inside such a device so as to be capable of effectively occluding the hemorrhoidal tissues. It is apparent that the pivoting jaws of the pliers-type

staplers of Yoon (all except Figure 28) and the U-shaped jaws of Figure 28 would be difficult if not impossible to use effectively inside the Leisenring speculum.

It is to be noted that applicant's claims speak of C- or U-shaped jaws. Applicant respectfully contravenes the Examiner's assertion that Figure 1 of Yoon discloses C- or U-shaped jaws. Rather, that embodiment of Yoon includes linear or straight jaws. However, as indicated above, Figure 28 shows U-shaped jaws. The U-shaped Yoon jaws are not conducive to occluding hemorrhoidal tissues in part because opening the jaws would be impeded by the curved wall of the Leisenring speculum. Alternatively and additionally, the hemorrhoidal tissues could not be occluded at their base. One of ordinary skill in the art would be motivated not to use the Yoon stapler in the Leisenring speculum.

Accordingly, applicant requests reconsideration of the rejection of claim 20.

**Dependent Claims 48-50** In order to further distinguish applicant's invention over the teachings and implications of Yoon and Leisenring, applicant adds new claims 48-50 dependent from claim 20.

Claim 48 recites that the manipulating of said occlusion device includes manipulating the occlusion device so that one of the jaws is located on a far or distal side of the hemorrhoidal tissues, between the hemorrhoidal tissues and an inner or distal end of the anoscope, and so that another of the jaws is located on a near or proximal side of the hemorrhoidal tissues, between the hemorrhoidal tissues and an outer or proximal end of the anoscope. None of the staplers of Yoon can accomplish this action.

Claim 49 sets forth that the closing of the jaws includes linearly translating at least one of the jaws towards the other of the jaws.

To clarify the U-shaped structure of applicant's jaws, applicant states in claim 50 that jaws define a U-shaped occlusion area. The tissues are occluded along an arcuate region.

**Independent Claim 30** As set forth in claim 30, a surgical instrument assembly for the treatment of hemorrhoids comprises, in accordance with the present invention, an anoscope and a hemorrhoid occlusion device, where the anoscope includes a hollow body closed at a distal end and at least partially open at a proximal end to define a longitudinal channel. The hollow body has a sidewall provided with a window spaced from at least the distal end. The hemorrhoid occlusion device includes an instrument shaft provided at a distal end with two jaws, at least one of the jaws including a C- or U-shaped clamping member movable alternately away and towards the other of the jaws for clamping and occluding hemorrhoidal tissues protruding through the window into the anoscope.

Applicant respectfully traverses the Examiner's rejection of claim 30, because one of ordinary skill in the art familiar with the teachings of Yoon and Leisenring would not be motivated to provide the instrument assembly of claim 30. Neither Yoon nor Leisenring suggests that the Yoon stapler could be used with the Leisenring speculum. Neither Yoon nor Leisenring suggests that a stapler would be beneficial or desirable in the treatment of hemorrhoids. Leisenring suggests, if anything, that hemorrhoids are to be treated with gentle care (needles are minimally invasive instruments) and stapling protruding hemorrhoids is hardly a gentle operation.

One of ordinary skill in the art would not feel inclined to use any of the Yoon staplers with the speculum of Leisenring in part since the proper use of the Yoon staplers would be blocked or impeded by the cramped and curved space of the speculum. It is apparent that the pivoting jaws of the pliers-type staplers of Yoon (all except Figure 28) and the U-shaped jaws of Figure 28 would be difficult if not impossible to use effectively inside the Leisenring speculum.

Again, applicant's claim 30 recites C- or U-shaped jaws. Applicant respectfully contravenes the Examiner's assertion that Figure 1 of Yoon discloses C- or U-shaped jaws. Rather, that embodiment of Yoon incorporates only *linear* or *straight* jaws.

However, as indicated above, Figure 28 of the Yoon patent shows U-shaped jaws. The U-shaped Yoon jaws are not conducive to occluding hemorrhoidal tissues in part because opening the jaws would be impeded by the curved wall of the Leisenring speculum. Alternatively and additionally, the hemorrhoidal tissues could not be occluded at their base if one were to use the stapler of Yoon Figure 28. One of ordinary skill in the art would be motivated *not* to use the Yoon stapler in the Leisenring speculum. The Leisenring speculum would *block* or *impede* the operation.

**Independent Claim 44** As set forth in previously presented claim 44, a surgical method utilizes (a) a hollow member having a peripheral wall provided with a window and (b) a closure member slidably connectable to the hollow member for alternately covering and uncovering the window. The method comprises inserting, into a patient, the hollow member and the closure member, the closure member covering the window during the inserting of the hollow member and the closure member. Thereafter the cover member is shifted relative to the hollow member, thereby allowing tissues of the patient to protrude into the hollow member via the window. Subsequently, a portion of the protruding tissues is clamped between a pair of jaws. A tissue occlusion device in the jaws is actuated to effectuate a coupling of the protruding tissues. Then the jaws are opened to release the tissues. Thereafter the hollow member and the closure member are withdrawn from the patient, the tissues passing back through the window during this withdrawal process.

Claim 44 distinguishes over the prior art as represented by Yoon and Leisenring for the reasons set forth above. One of ordinary skill in the art would not be motivated by Yoon and Leisenring to practice applicant's method. Yoon and Leisenring provide no teaching or suggestion to one of ordinary skill in the art to staple hemorrhoidal tissues. To the contrary, Leisenring is concerned about avoiding damage or injury to the hemorrhoidal tissues and specifically mentions only using a needle, which clearly avoids injury or trauma to the tissues. Moreover, one of ordinary skill in the art would not

contemplate using the Figure 28 stapler (or any another embodiment) of Yoon with the Leisenring speculum since to do so also impede the proper use of the stapler and prevent proper occlusion of the hemorrhoidal tissues. The staplers of Yoon are not designed to perform an operation on a surgical site inside a tubular member.

**Independent Claim 45** New independent claim 45 includes essential limitations from claims 30 and distinguishes over Yoon and Leisenring for the reasons discussed above. In addition, claim 45 recites a structural feature of the anoscope which does not appear in the Leisenring speculum and further distinguishes applicant's invention over Yoon and Leisenring. That feature is the ***bulge in the sidewall*** of the anoscope body, the sidewall window being disposed particularly in the bulge or protrusion. As described in applicant's specification, the bulging portion of the anoscope serves as a retractor of collateral anal/rectal tissues. In addition, the protrusion creates more workspace in the area of hemorrhoid. This design allows for better access to the base of the hemorrhoid, which is located in the submucosal layer close to the rectal muscle.

Neither Yoon nor Leisenring discloses or suggests an instrument assembly comprising an anoscope and an occlusion device wherein the anoscope has a sidewall formed with a ***bulge or protrusion provided with a window***.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

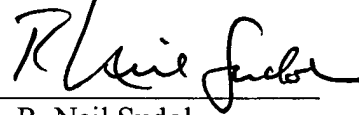
### ***Conclusion***

For the foregoing reasons, independent claims 20, 30, 44, and 45, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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